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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT PAPER NUMBER

1651

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,406	SCHOLTHAUER ET AL.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6-4-02, 7-16-02, 4-8-03</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The preliminary amendment filed August 9, 2004, has been received and entered.

Claims 1-34 are pending and are examined on the merits.

Priority

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in New Zealand on June 17, 1998. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the New Zealand application was filed more than twelve months before the international application on which this U.S. national phase application is based.

Claim Objections

Claims 8 and 11-32 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may depend from previous claims in the alternative only (claim 8), and because a multiple dependent claim may not depend from another multiple dependent claim (claims 11-32). See MPEP § 608.01(n). Note that, while MPEP 608.01(n) provides that improper multiple dependent claims need not be treated on the merits, the cited claims have been treated on the merits to the

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extent possible, given the numerous possible combinations of limitations provided for in the claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20, 21 and 31 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "to avoid substantial denaturation of peptides" in claim 1 is indefinite. It is not clear whether the term "avoid" excludes all processes which contains denaturation, or whether some degree of denaturation is acceptable, since only avoidance is required, and not absolute exclusion. Also, because of the subjective nature of the term, it is not clear how much denaturation is encompassed by the term "substantial", since the an amount of denaturation considered substantial by one practitioner might not be considered substantial by another.

The recitation "wherein the production of the process is highly soluble" in claim 1 is also indefinite. First, it appears that applicant should be referring to the -- product -- of the process, not the "production." Second, it is not clear what solubility levels are encompassed by the relative term "highly" and what solubility levels are not encompassed by the term. Note that the indefinite term "highly soluble" appears in the claims at several locations.

Claim 2 is confusing, and therefore indefinite, because it recites that the enzyme can be any one of a group of specific commercial proteases, or "can be any other heat labile protease." This is confusing, since claim 2 depends from claim

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1, and claim 1 already requires the enzyme to be a heat labile protease. Thus, the confusion lies in the fact that it is not clear how claim 2 further defines claim 1.

As discussed above, claims 8 and 11-32 are improper multiple dependent claims. These claims are also considered indefinite because the improper multiple dependencies render the metes and bounds of the unclear, since it is unclear which set of limitations must be present at any one time.

Claims 20, 21 and 31 provide for the use of certain claimed products, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Schlothauer et al (WO 99/65326).

Schlothauer describes the production of polypeptides from whey using neutral proteases including Neutrase (see, e.g., claims 6-8 on page 20), acid proteases (see Example 14 on pages 13 and 14), and alkaline proteases (see page 5, lines 15-16). Schlothauer describes the claimed variety of deactivation methods recited in claims 5-10 (see, e.g., pages 5-6), as well as the claimed immobilization techniques (page 5, lines 5-8). Schlothauer further discloses the preparation and use of the peptide MKG as recited in claims 15, 18, 21, 27 and 33 (see, e.g., page 4, lines 33-36), and the peptide combinations recited in claim 16, 28 and 34 are considered to be inherently met by Schlothauer by virtue of the fact that the same enzymes are contacted with the same substrate to achieve the same degree of hydrolysis. A holding of anticipation is clearly required.

Claims 1, 2, 3, 9, 10, 13-18, 20-23, 26-29 and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Mullally et al (Int. Dairy Journal 7:299-303 (1997)).

Mullally discloses a process whereby whey protein concentrate containing 4.7% lactose (see page 300, paragraph entitled "Substrates") is contacted with a protease at a

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temperature of 50 degrees C at a pH of 8 to a degree of hydrolysis ranging from 0 to 8% (see Fig. 1, page 301), followed by heat inactivation of the enzyme (see page 300, paragraph entitled "Pilot-scale hydrolysis of WPC"), followed by assaying of ACE inhibitory activity (see, e.g., Fig. 1, page 301).

Mullally also processes the resulting hydrolysate by ultrafiltration with a 10 kD cutoff membrane. See, e.g., Table 2 on page 302. Note also the disclosure in Table 1 of the use of acid proteases and other proteases. Mullally therefore anticipates the cited claims.

Lastly, note that Mullally is considered to anticipate the product claims because the same substrate as claimed is contacted with the same enzyme as claimed under the same conditions as claimed to make a product having the same degree of hydrolysis as recited in the claims. The resulting hydrolysate product must therefore be the same, including the presence of the claim-recited peptides. If there is a difference between the prior art and the claims, it must be due to some aspect of the process not recited in applicant's claims.

Claims 1, 2, 7, 13-18, 20-23, 26-29 and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Mellqvist et al (U.S. Pat. 4,847,096).

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Mellqvist discloses a process of improving the taste and storage stability of whey proteins, whereby a whey protein concentrate is contacted with a protease, Alcalase, at 50°C and pH 8 to a degree of hydrolysis of 2.2, after which the enzyme is inactivated by decreasing pH to 4 for 60 min. See column 3, lines 35-45. Mellqvist also discloses the preparation of a peptide hydrolysate with a degree of hydrolysis of 4.1% from whey protein concentrate using Alcalase (Example 3, at column 4). A holding of anticipation over the cited claims is therefore required.

Lastly, note that Mellqvist is considered to anticipate the product claims because the same substrate as claimed is contacted with the same enzyme as claimed under the same conditions as claimed to make a product having the same degree of hydrolysis as recited in the claims. The resulting hydrolysate product must therefore be the same, including the presence of the claim-recited peptides. If there is a difference between the prior art and the claims, it must be due to some aspect of the process not recited in applicant's claims.

Claims 1-34 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/720,041 which has a common inventor with the instant

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application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

The '041 application describes the production of polypeptides from whey using neutral proteases including Neutrase (see, e.g., claims 6-8 on page 20 of the published PCT application), acid proteases (see Example 14 on pages 13 and 14 of the published PCT application), and alkaline proteases (see page 5, lines 15-16 of the published PCT application).

The '041 application describes the claimed variety of deactivation methods recited in claims 5-10 (see, e.g., pages 5-6), as well as the claimed immobilization techniques (page 5, lines 5-8). The '041 application further discloses the preparation and use of the peptide MKG as recited in claims 15, 18, 21, 27 and 33 (see, e.g., page 4, lines 33-36), and the peptide combinations recited in claim 16, 28 and 34 are considered to be inherently met by the '041 application by virtue of the fact that the same enzymes are contacted with the same substrate to achieve the same degree of hydrolysis. A holding of anticipation is clearly required.

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This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35

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U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mullally et al (Int. Dairy Journal 7:299-303 (1997)) in view of Abubakar et al (Tohoku Journal of Agricultural Research 47(1-2):1-8 (1996)).

As discussed above, Mullally discloses a process whereby the whey protein concentrate is hydrolyzed by proteases and the resulting hydrolysate is tested for ACE inhibiting activity. Mullally differs from the claims in failing to use all of the claimed proteases recited in applicant's claim 2. However, in view of the combined disclosures of Mullally and Abubakar, demonstrating that a large variety of proteases having different specificities all result in the production of ACE-inhibiting peptides from whey protein, the claimed use of commercially available proteases must be considered obvious under § 103(a).

Further still, the determination of suitable parameters for heat and/or pH-based enzyme inactivations (applicants' claims 4-8) for the processes of Mullally and Abubakar would have been obvious in view of the fact that such methods of enzyme inactivation are notoriously well known in the enzymology arts, the determination of suitable or effective parameters in such processes being routinely optimized by those skilled in the art.

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Still further, the use of immobilized enzymes (applicant's claims 11-12) is well known in the art, and would have been obvious in view of the disclosures of Mullally and Abubakar. Further still, the use of the hydrolysates of Mullally in the treatment of hypertension, encompassed by claims 19 and 30, clearly would have been obvious in view of the disclosure of both Mullally and Abubakar that protease-hydrolyzed whey hydrolysates possess ACE-inhibiting peptides. Still further, the determination of a suitable substrate particle size (applicant's claims 24-26) in Mullally's process clearly would have been a matter of routine optimization on the part of the artisan of ordinary practicing Mullally's process, said artisan clearly recognizing that particle size would influence not only the hydrolysis process, but also the properties of the product ultimately produced by that process. A holding of obviousness over the cited claims is therefore required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No.

09/720,041 Although the conflicting claims are not identical, they are not patentably distinct from each other because all of the process steps recited in the claims under examination herein are recited in the claims of the copending patent application. Similarly, because the processes in the two sets of claims recite contacting essentially the same starting material with the same enzymes, the resulting products must necessarily be the same. Thus, although the scope of the two sets of claims is not identical, a terminal disclaimer is properly required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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As discussed above, claims 1-34 are directed to an invention not patentably distinct from the claims of commonly assigned Application Serial No. 09/720,041. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 09/720,041, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'F. Prats', with a large, stylized initial 'F'.

Francisco C Prats
Primary Examiner
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FCP